

<b>Notice of Allowability</b>	Application No.	Applicant(s)
	10/627,451	GRAFF ET AL.
	Examiner	Art Unit
	Devesh Khare	1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 6/24/2004.
2.  The allowed claim(s) is/are 1-5 and 7-17.
3.  The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

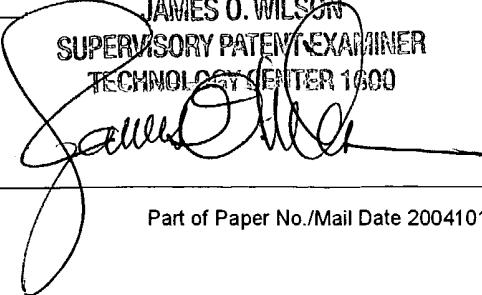
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of
 Paper No./Mail Date \_\_\_\_\_.
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review ( PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date 10/13/2004.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_

**JAMES O. WILSON**  
 SUPERVISORY PATENT EXAMINER  
 TECHNOLOGY CENTER 1600



Applicant's remarks filed on 06/24/04 in response to the Office Action dated 02/25/04 are acknowledged.

The rejection of claims 1-5 and 7-17, under 35 U.S.C., 112, second paragraph, has been overcome through the examiner's amendments.

A Declaration under 37 C.F.R. 1.132, executed by Jonathan Michael Graff, the inventor of the present application has been entered.

The examiner withdraws the 35 U.S.C. 103(a) rejections, as being unpatentable over Flotte et al. in view of Hu et al. in response to applicant's remarks that "The Hu patent does not suggest to those skilled in the art that such enterically delivered aminoglycosides could provide effective therapy for colorectal neoplasia, and Flotte's method for using high-pressure impulse transients to promote drug delivery does not somehow complement Hu to provide such suggestion".

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given by Richard Osman on 10/13/04.

(1) Claims 6 and 18-20 have been cancelled without prejudice.

(2) Claims 16 and 17 depend from claim 15.

(3) Claims 1,5,7,13 and 14 have been amended as following:

1. (Currently Amended) A method of reducing development of colorectal neoplasia in a patient subject or predisposed to colorectal neoplasia, the method comprising the steps of:

determining a patient is subject or predisposed to colorectal neoplasia, or has undergone removal or ablation of a colorectal neoplasia; and

enterically delivering into the gut of the person an effective amount of an aminoglycoside antibiotic having poor gut absorption, whereby the development of the colorectal neoplasia is reduced as compared with otherwise similar non-treated patients.

5. (Currently Amended) The method of claim 1, wherein the patient has undergone removal or ablation of a colorectal neoplasia ~~and is determined to be predisposed to colorectal neoplasia recurrence.~~

7. (Currently Amended) The method of claim 1, wherein the aminoglycoside antibiotic is selected from the group consisting of: Amikacin (Amikin<sup>®</sup>), Gentamicin (Garamycin<sup>®</sup>), Kanamycin (Kantrex<sup>®</sup>), Neomycin (Mycifradin<sup>®</sup>), Netilmicin (Netromycin<sup>®</sup>), Paromomycin (Humatin<sup>®</sup>), Streptomycin, and Tobramycin (TOBI Solution<sup>®</sup>, TobraDex<sup>®</sup>, Nebcin<sup>®</sup>).

13. (Currently Amended) The method of claim 1, wherein the delivering step is effected by delivering a constant ~~over time~~ dosage of the aminoglycoside.

14. (Currently Amended) The method of claim 1, wherein the delivering step is effected by delivering a varying ~~over time~~ dosage of the aminoglycoside.

Claims 1-5 and 7-17 are currently pending in this application.

Claims 1-5 and 7-17 are allowed.

2. The following is an examiner's statement of reasons for allowance: The instant claims are directed to a method of reducing development of colorectal neoplasia in a patient subject or predisposed to colorectal neoplasia comprising the steps of : determining a patient is subject to colorectal neoplasia, or has undergone removal or ablation of a colorectal neoplasia; and enterically delivering into the gut of the person an effective amount of an aminoglycoside antibiotic having poor gut absorption, whereby the development of the colorectal neoplasia is reduced as compared with otherwise

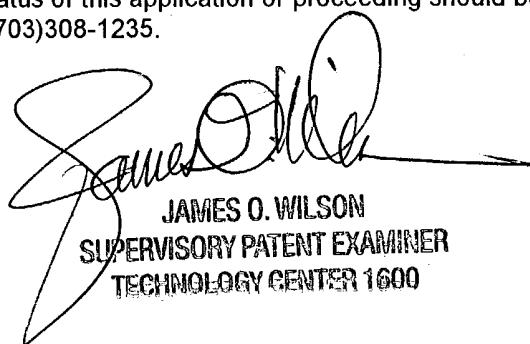
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similar non-treated patients, is not taught or fairly suggested by the prior art of the record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

Devesh Khare, Ph.D.,J.D.  
Art Unit 1623  
October 15,2004



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